

MR-1 REPORT CHECK OFF LISTCompany : **Amneal Pharmaceuticals Corp.**

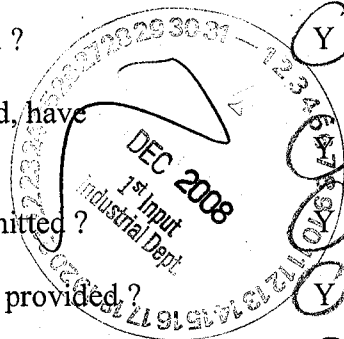
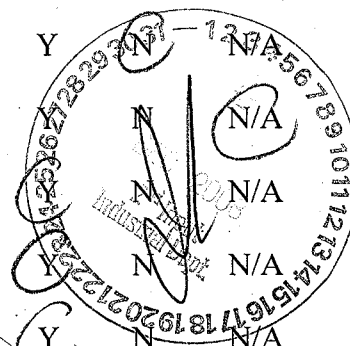
SCP #: 27200050-1

Address : 290 McClean Blvd., Paterson, NJ 07504

Contact : Jiten Parikh

973-357-0222

- | | | | | |
|-----|---|------------------------------------|------------------------------------|-----|
| 1. | Category 40 CFR 439.47 (b) Subcategory | D | | |
| 2. | MONTH OF SEPTEMBER 1, 2008 THRU SEPTEMBER 30, 2008 | | | |
| 3. | Is Outlet # (8 digit) Correct ? | <input checked="" type="radio"/> Y | N | N/A |
| 4. | Is regulated flow stated in space provided ? | <input checked="" type="radio"/> Y | N | N/A |
| 5. | Total flow provided in proper space ? | <input checked="" type="radio"/> Y | N | N/A |
| 6. | Is method used to calculate water stated,? | <input checked="" type="radio"/> Y | N | N/A |
| 7. | Are number of working days stated ? | <input checked="" type="radio"/> Y | N | N/A |
| 8. | Are there any parameters which have exceeded a daily maximum limit or could cause the company to be out of compliance with a monthly or 4-day average ? | Y | <input checked="" type="radio"/> N | N/A |
| 8a | Are any non-detectable results higher than the permits limits ? | Y | <input checked="" type="radio"/> N | N/A |
| 8b | If the answer to 8a was yes. did the company submit any documentation in support of compliance ? | | <input checked="" type="radio"/> N | N/A |
| 9. | Is proper compliance/non-compliance statement provided ? | | <input checked="" type="radio"/> N | N/A |
| 10. | If applicable is compliance schedule submitted ? | | <input checked="" type="radio"/> N | N/A |
| 11. | Is combined waste stream formula required ? | <input checked="" type="radio"/> Y | N | N/A |
| 12. | If combined waste stream formula was used, have calculations been submitted correctly ? | | N | N/A |
| 13. | Have correct number of samples been submitted ? | | N | N/A |
| 14. | Has sample number been reported in space provided ? | <input checked="" type="radio"/> Y | N | N/A |
| 15. | Have all regulated parameters been listed on MR-1 ? | <input checked="" type="radio"/> Y | N | N/A |
| 16. | Has sample type been stated on MR-1 ? | <input checked="" type="radio"/> Y | N | N/A |
| 17. | Have all samples been taken during this reporting period ? | <input checked="" type="radio"/> Y | N | N/A |
| 18. | Has NJDEPE certified lab been used ? | <input checked="" type="radio"/> Y | N | N/A |
| 19. | Have analytical results been submitted on copies of Laboratory stationery ? | <input checked="" type="radio"/> Y | N | N/A |



- | | | | | |
|------|--|------------------------------------|------------------------------------|--------------------------------------|
| 20. | Have results been written in space designated on MR-1? | <input checked="" type="radio"/> Y | N | N/A |
| 21. | Have average permit limitations been included on MR-1? | <input checked="" type="radio"/> Y | N | N/A |
| 22. | Have maximum permit limitations been included on MR-1? | <input checked="" type="radio"/> Y | N | N/A |
| 23. | Is method used to preserve samples stated on MR-1? | <input checked="" type="radio"/> Y | N | N/A |
| 24. | If non-use statement is made does regulations allow exemptions ? | Y | <input checked="" type="radio"/> N | N/A |
| 25. | Has updated flow diagram been provided ? | Y | N | <input checked="" type="radio"/> N/A |
| 26. | If the answer to 25 was yes, was the change to the previous plot plan noted ? | Y | N | <input checked="" type="radio"/> N/A |
| 27.. | If the answer to 25 was no or N/A, was the appropriate statement of no-change to diagram submitted ? | <input checked="" type="radio"/> Y | N | N/A |
| 28. | Has production rate been provided if production Based Standards were used ? | Y | N | <input checked="" type="radio"/> N/A |
| 29. | Has MR-1 been signed by authorized representative ? | <input checked="" type="radio"/> Y | N | N/A |
| 29. | Has information been submitted on proper MR-1 form ? | <input checked="" type="radio"/> Y | N | N/A |
| 29. | Have any and all PVSC samples taken during this month been averaged in with the company samples ? | Y | N | <input checked="" type="radio"/> N/A |

First Reviewer: comments on deficiencies COMPLETE

Date Reviewed 12/2/08 Date sent to user _____

Date due back _____ Reviewer e.j.m.

Second Review comments on deficiencies _____

Date Reviewed _____ Date sent to user _____

Date due back _____ Reviewer _____

Date ok _____ Reviewer _____

09/01/08 THRU 09/30/08

AMNEAL PHARMACEUTICALS

(439)

PATERSON

Local Limits

Parameters	Threshold Value	Local Limit	Over Limit	Additional Tests
Cadmium	0.005	0.19	Certified Non-Use	None
Copper	0.092	3.02		Three Months
Lead	0.029	0.54		
Nickel	0.02	5.9	Certified Non-Use	None
Zinc	1.67	1.67		
Mercury	0.001	0.080		Three Months

Violations: noneCOMPLETE ☒ Yes ☐ NoDate 12/2/08

PRETREATMENT MONITORING REPORT

NAME: AMNEAL PHARMACEUTICALS CORPORATION PST-2101-2008

MAILING ADDRESS: 209 MC LEAN BLVD., PATERSON, NJ 07504

FACILITY LOCATION: 209 MC LEAN BLVD., PATERSON, NJ 07504

CATEGORY & SUBPART: 439 OUTLET #: 1

CONTACT OFFICIAL: JITEN PARIKH TELEPHONE: 973 357-0222

NEW CUSTOMER ID / OUTLET ID: 272-00050-1 OLD OUTLET DESIGNATION: _____

MONITORING PERIOD					
Start			End		
09	01	08	09	30	08
MO	DAY	YR	MO	DAY	YR

Average Maximum

Regulated Flow-gal/day 1306 1436

Total Flow-gal/day 3142 3456

Method Used: _____ Flowmeter readings / working days. _____

PLEASE SEE ATTACHMENT

Production Rate (if applicable) _____

PARAMETER		MASS OR CONCENTRATION			# OF SAMPLES	SAMPLE TYPE COMP/GRAB
		MON AVG	MAXIMUM	UNITS		
Cd	Sample Measurement	ND (<0.002)		Mg/l	1	Comp
CADMIUM	Permit Requirement	0.19		Mg/l		
Cu	Sample Measurement	0.0254 ✓		Mg/l	1	Comp
COPPER	Permit Requirement	3.02		Mg/l		
Pb	Sample Measurement	0.008		Mg/l	1	Comp
LEAD	Permit Requirement	0.54		Mg/l		
Hg	Sample Measurement	ND (<0.002)		Mg/l	1	Comp
MERCURY	Permit Requirement	0.080		Mg/l		
Ni	Sample Measurement	0.0034		Mg/l	1	Comp
NICKEL	Permit Requirement	5.9		Mg/l		
Zn	Sample Measurement	0.0778 ✓		Mg/l	1	Comp
ZINC	Permit Requirement	1.67		Mg/l		
ACETONE	Sample Measurement	0.913 ✓		Mg/l	1	Grab
	Permit Requirement	8.2		Mg/l		
METHYLENE CHLORIDE	Sample Measurement	ND (<0.0033)		Mg/l	1	Grab
	Permit Requirement	0.7		Mg/l		
ETHYL ACETATE	Sample Measurement	ND (<0.005)		mg/L		Grab
	Permit Requirement	8.2		mg/L		
ISOPROPYL "	Sample Measurement	ND (<0.005)		mg/L		Grab
	Permit Requirement	8.2		mg/L		
n-AMYL ACETATE	Sample Measurement	ND (<0.005)		mg/L		Grab
	Permit Requirement	8.2		mg/L		
	Sample Measurement					
	Permit Requirement					
	Sample Measurement					
	Permit Requirement					
	Sample Measurement					
	Permit Requirement					

PRETREATMENT MONITORING REPORT

OCT 20 2008

Certification of Non-Use if applicable (use additional sheets):

N/A

Compliance or non compliance statement with compliance schedule (use additional sheets if necessary) for every

parameter used: AMNEAL IS IN COMPLIANCE WITH PVSC LOCAL
LIMITS AS WELL AS ALL 40 CFR 439 PARAMETERS.Explain Method for preserving samples: NITRIC ACID TO A PH LESS THAN 2.

I certify under penalty of law that this document and attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

403.6(a)(2)(ii) revised by 53 FR 40610, October 17, 1988

Semen Roxas

Signature of Principal

Executive or Authorized Agent

for: JITEN PARIKH
VICE PRESIDENT

Type Name and Title

10-15-08

Date



METHOD USED

TOTAL WATER USED

$7,211.5 (9/30/08) - 7,119.1 (9/1/08) = 92 \text{ CF1} \times 7.48 \times 100 = 69,115/22 \text{ DAYS} = 3,142 \text{ Total Flow - Gal/Day.}$

SANITARY USED

$1,564 (9/30/08) - 1,510 (9/1/08) = 54 \times 7.48 \times 100 = 40,392/22 \text{ DAYS} = 1,836 \text{ Flow - Gal/Day.}$

$$\text{REGULATORY/TOTAL} = 1,306/3,142 = 0.4$$

SITE PLAN: NO CHANGE

Ms. Sonal Thakar
Amneal Pharmaceutical Corp..
209 McLean Blvd
Paterson, NJ 07054

ANALYSIS REPORT

REPORT DATE: SEPT.24, 2008

PROJECT NO : 813760

LAB ID NO: 813760.1

FIELD ID NO: AP-0916

Sample: Liquid, Sampled by Customer on 9/16/08

Analysis	Method Number	Results (mg/L)	Discharge Limitation (mg/L)	RLs (mg/L)	Analysis Date Time	DF
CADMIUM	200.8	ND(<0.002)	0.19	0.002	9/22/08 15:11	1
COPPER	200.8	0.0254	3.02	0.002	9/22/08 15:11	1
NICKEL	200.8	0.0034	5.9	0.002	9/22/08 15:11	1
LEAD	200.8	0.008	0.54	0.002	9/22/08 15:11	1
ZINC	200.8	0.0778	1.67	0.005	9/22/08 15:11	1
MERCURY	245.1	ND(<0.0002)	0.080	0.0002	9/19/08 16:49	1

Definitions:

pH Unit, J= Compound Detected but Below MDL, **RLs**= Laboratory Reporting Limits,
MDL= Method Detection Limit, **DF**= Dilution Factor, **ND** = Not Detected, **RL** = MDL x DF
All metal analyses performed were subcontracted to NJ certified lab # PA 166

Submitted By:



Zvi Blank, Ph.D., CHMM
Laboratory Director



Ms. Sonal Thakar
Amneal Pharmaceutical Corp..
209 McLean Blvd
Paterson, NJ 07054

ANALYSIS REPORT

REPORT DATE: SEPT. 26, 2008

PROJECT NO : 813760

LAB ID NO: 813760.2

FIELD ID NO: AP-0916 G

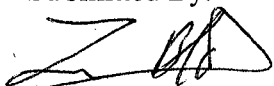
Sample: Liquid, Sampled by CALI on 9/16/08

Analysis	Method Number	Results (µg/L)	Discharge Limitation (mg/L)	RLs (µg/L)	Analysis Date	DF
ACETONE	EPA Method 624	913	8.2	16.7	9/22/08	1
METHYLENE CHLORIDE	EPA Method 624	ND(<3.30)	0.7	3.30	9/22/08	1

Definitions:

pH Unit, J= Compound Detected but Below MDL, **RLs**= Laboratory Reporting Limits,
MDL= Method Detection Limit, **DF**= Dilution Factor, **ND** = Not Detected, **RL** = MDL x DF
Analyses performed were subcontracted to NJ certified lab # 07010

Submitted By:



Zvi Blank, Ph.D., CHMM
Laboratory Director



Ms. Sonal Thakar
Amneal Pharmaceutical Corp..
209 McLean Blvd
Paterson, NJ 07054

ANALYSIS REPORT

REPORT DATE: SEPT. 26, 2008

PROJECT NO : 813760

LAB ID NO: 813760.1

FIELD ID NO: AP-0916G

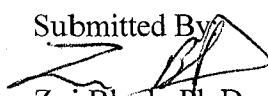
Sample: Liquid, Sampled by Customer on 9/16/08

Analysis	Method Number	Results (µg/L)	Discharge Limitation (mg/L)	RLs (µg/L)	Analysis Date	DF
Ethyl Acetate	EPA Method 624	ND(<5)	8.2	5	9/19/08	1
Isopropyl Acetate	EPA Method 624	ND(<5)	8.2	5	9/19/08	1
n-Amyl Acetate	EPA Method 624	ND(<5)	8.2	5	9/19/08	1

Definitions:

pH Unit, J= Compound Detected but Below MDL, RLs= Laboratory Reporting Limits,
MDL= Method Detection Limit, DF= Dilution Factor, ND = Not Detected, RL = MDL x DF
Analyses performed were subcontracted to NJ certified lab # 07010

Submitted By


Zvi Blank, Ph.D., CHMM
Laboratory Director





QC Laboratories®

Analytical Report



MS. HAYA BLANK
COMPLETE ANALYSIS LABORATORIES, INC.
1259 ROUTE 46
BUILDING #4/C
PARSIPPANY, NJ 07054-4909

Regarding:

MS. HAYA BLANK
COMPLETE ANALYSIS LABORATORIES, INC.
1259 ROUTE 46
BUILDING #4/C
PARSIPPANY, NJ 07054-4909

Account No: W05307, COMPLETE ANALYSIS 1 WK TAT PHILLY QA
Project No: W05307, COMPLETE ANALYSIS 1 WK TAT PHILLY QA

P.O. No:
PWSID No:

Inv. No: 1009300

Sample Number L2777257-1
Sample Description 813760.1 COMPOSITE
Received Temp: 38 F Iced (Y/N): Y

Samp. Date/Time/Temp 09/16/08 12:45pm NA F
Sampled by Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
CADMIUM	EPA 200.8	ND mg/l	0.00200 mg/l	09/22/08 03:11PM GJH
COPPER	EPA 200.8	0.0254 mg/l	0.00200 mg/l	09/22/08 03:11PM GJH
NICKEL	EPA 200.8	0.00340 mg/l	0.00200 mg/l	09/22/08 03:11PM GJH
LEAD	EPA 200.8	0.00800 mg/l	0.00200 mg/l	09/22/08 03:11PM GJH
ZINC	EPA 200.8	0.0778 mg/l	0.00500 mg/l	09/22/08 03:11PM GJH
MERCURY	EPA 245.1	ND mg/l	0.000200 mg/l	09/19/08 04:49PM CMC

- A result of "ND" indicates the concentration of the analyte tested was either not detected or below the RLs.
- Definitions: ND=not detected; NEG=negative; POS=positive; COL=colonies; RLs=laboratory reporting limits; L/A=laboratory accident; TNTC=too numerous to count
- A result marked with "DRY" indicates that the result was calculated and reported on a dry weight basis.
- All analysis, except field tests are conducted in Southampton, PA unless otherwise identified.
- The test "pH lab" is analyzed upon receipt at the laboratory, the result will not be suitable for regulatory purposes.
- Actual times of analysis for parameters reported <24 hrs are available upon request. All testing is completed within the required holding time unless otherwise noted.
- QC NELAP ID's: PA 09-00131, NJ PA166, FL E87954, NY 11223, CT PH-0768, DE PA-018, KY 90228, MD 206, EPA PA00018, Bioassay: PA 09-03574, NJ PA034, FL E87953, KS E10373, SC 89020001.
- QC STATE ID's: Wind Gap, NJ PA001, PA 48-01334; E RUTHERFORD NJ02015; Vineland NJ06005; Reading PA 06-03543.
- All samples are collected as "grab" samples unless otherwise identified.
- MCL= is the EPA recommended "maximum contaminant level" for a parameter. PLs=customer specific permit limits.
Regulatory authorities are assessing substantial fines for testing omissions. Please track your sample collections and results on a weekly, monthly, or quarterly basis to ensure compliance. QC's internet program 'LIVE ACCESS' will provide you with real-time access to collection dates and results. Please contact Customer Service for further information on acquiring LIVE ACCESS.

Thomas J. Hines
Thomas J. Hines, President

Aqua Pro-Tech Laboratories
EPA Method 624 Analytical ReportClient: Complete Analysis
Project:
Matrix: Wastewater

Client Sample:

813760.2 1:10

Lab Sample ID: 28090609-001
Lab File ID: 4V1660.D
Date Collected: 16-Sep-08Date Analyzed: 22-Sep-08
Dilution Factor: 10

CAS No.	Compound	Conc ug/L	Q	MDL	PQL
67-64-1	Acetone	913	D	16.7	50
75-09-2	Methylene Chloride		U	3.30	50

AQUA PRO-TECH LABORATORIES
EPA Method 624 Acetates Report

Client Sample

WastewaterClient: Complete Analysis
Project: _____Matrix: Water
Sample wt/vol: 5.0 (g/mL) mL
Level: LOWLab Sample ID: 28090609-001
Lab File ID: 4V1614.D
Date Collected: 9/16/2008
Date Analyzed: 9/19/2008
Dilution Factor: 1.0

COMPOUND	CONCENTRATION		Q	RL
	ug/L			
Ethyl Acetate			U	5
Isopropyl Acetate			U	5
n-Amyl Acetate			U	5

Qualifiers: U - Undetected, D - Diluted, RL - Reporting Limit

CHAIN OF CUSTODY

COMPLETE ANALYSIS LABORATORIES, INC.

1259 ROUTE 46 BLDG. # 4
 PARSIPPANY, NJ 07054-4909
 PHONE: (973) 335-CALI
 FAX: (973) 335- 0556
 NJDEP LAB CERTIFICATION # 14964

PAGE 1 OF 1
 (Lab use only) No. 813760

DELIVERABLES: ☒ STD ☐ REDUCED ☐ FULL
 (CIRCLE ONE) OTHER (Specify) _____

CLIENT	AMNEAL PHARMACEUTICAL		
ADDRESS	209 MCLEAN BLVD.		
CITY	PATERSON		
STATE	NJ	ZIP	07054

CONTACT	DR. ZIRVI	PHONE	(973) 357-0222
PROJECT	WASTEWATER		
SAMPLER	name <u>Albert Serrano</u>		sign <u>[Signature]</u>
WITNESSED BY	name <u>SR 9-16-08</u>		

LAB ID	FIELD ID	SAMPLING DATE/TIME	M	T	No	P	ANALYSIS
813760.1	AP- 0916	9/16/08 12:44	A	C	1	C	BOD, TSS
813760.1	AP- 0916	9/16/08 12:45	A	C	1	Hn, C	Ni, Zn, Cd, Pb, Cu, Hg
813760.2	AP- 09166	9/16/08 12:48	A	G	2	H, C	VOC*
REMARKS	* VOC TO INCLUDES: ACETONE, n-AMYL ACETATE, ETHYL ACETATE, ISOPROPYL ACETATE, METHYLENE CHLORIDE						
	COMPOSITE SAMPLER WAS SET UP ON <u>9/16/08 @ 12:30</u> ; SAMPLE WAS COLLECTED ON <u>9/16/08 @ 12:44</u>						
	SAMPLING FREQUENCY - 30 MINUTES. <u>Semi annual</u>						

RELINQUISHED BY		RECEIVED BY		DATE	TIME	METHOD OF RELINQUISH.	RECEIVING ORGANIZATION
NAME	SIGNATURE	NAME	SIGNATURE				
<u>C. M. Serrano</u>	<u>[Signature]</u>	<u>SR</u>	<u>[Signature]</u>	<u>9/16/08</u>	<u>14:30</u>	<u>note: no sample</u>	<u>CHS</u>
TURNAROUND TIME:				PRIORITY AUTHORIZATION:			
M = MATRIX	A - AQUEOUS SL-SLUDGE	P - POTABLE WATER SO - SOLID		S - SOIL X - OTHER		O - OIL	
T = TYPE	C - COMPOSITE G - GRAB		No. = NUMBER OF CONTAINERS				
P = PRESERVATIVE	H ₂ - H ₂ SO ₄ Hn-HNO ₃ H-HCl N-NaOH A-ASCORBIC ACID C - COOL TO 4 °C						

SOP-CG-010 REV 4/96

FOR REGULATORY COMPLIANCE

DROP DOWN BOX**NON USE CERTIFICATION MONITORING REPORT
LOCAL LIMITS**NAME: AMNEAL PHARM.

MAILING ADDRESS: _____

FACILITY LOCATION: _____

CATEGORY & SUBPART _____

PERMIT # _____

OUTLET #: 27200050-1

CONTACT OFFICIAL: _____

TELEPHONE #: _____

I have been authorized to certify non-use for the following heavy metals:

Arsenic _____ Lead ☒ Zinc _____Cadmium ☒ Mercury ☒

Chromium _____ Molybdenum _____

Copper _____ Nickel ☒

SAMPLE DATE

MONTH DAY YEAR

9 16 08

PARAMETER		CONCENTRATION			SAMPLE TYPE
		RESULT	THRESHOLD VALUE EXCEEDED YES OR NO	UNITS	COMP/GRAB
CADMIUM	Sample Measurement	<u>< 0.002</u> ✓		<u>mg/l</u>	Comp.
	Threshold Value	<u>0.005</u>		<u>1</u>	
LEAD	Sample Measurement	<u>0.008</u> ✓		<u>mg/l</u>	COMP.
	Threshold Value	<u>0.029</u>		<u>1</u>	
MERCURY	Sample Measurement	<u>< 0.0002</u> ✓		<u>mg/l</u>	COMP.
	Threshold Value	<u>0.001</u>		<u>1</u>	
NICKEL	Sample Measurement	<u>0.0034</u> ✓		<u>mg/l</u>	COMP.
	Threshold Value	<u>0.02</u>		<u>1</u>	
ETHYLACETATE	Sample Measurement	<u>< 0.005</u> ✓		<u>mg/l</u>	GRAB
	Threshold Value			<u>1</u>	
ISOPROPYLACETATE	Sample Measurement	<u>< 0.005</u> ✓		<u>mg/l</u>	GRAB
	Threshold Value			<u>1</u>	
METHYLENE CHLORIDE	Sample Measurement	<u>< 0.0033</u> ✓		<u>mg/l</u>	GRAB
	Threshold Value			<u>1</u>	
n-AMYLACETATE	Sample Measurement	<u>< 0.005</u> ✓		<u>mg/l</u>	GRAB
	Threshold Value			<u>1</u>	
	Sample Measurement				
	Threshold Value				

SB